EYE DROPS REGULAR- tetrahydrozoline hydrochloride solution/ drops KC Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredient

Tetrahydrozoline HCl 0.05%

Purpose

Tetrahydrozoline HCl.....Redness reliever

Use

■ relieves redness of the eye due to minor eye irritations

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface.

Replace cap after using.

- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lens before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for

more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

instill 1 to 2 drops in the affected eye(s) up to 4 times daily

Other information

store at 15°-30°C (59°-86°F)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, sodium chloride



Drug Facts Active ingredient Purpose Tetrahydrozoline HCI 0.05% ■ relieves redness of the eye due to minor eye irritations Warnings For external use only Ask a doctor before use if you have narrow angle glaucoma. When using this product pupils may become enlarged temporarily ■ to avoid contamination, do not touch tip of container to any surface. Replace cap after using. ■ if solution changes color or becomes cloudy, do not use overuse may produce increased redness of the eye remove contact lens before using Stop use and ask a doctor if you experience eve pain changes in vision continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours If pregnant or breast-feeding, ask a health professional before

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"This product is not manufactured or distributed by Johnson & Johnson, Healthcare Products, distributor of Visine® Original.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED NECKBAND IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Compare to the active ingredient in Visine® Original*

Medic's Choice.

EYE DROPS

ORIGINAL

0.5 fl. oz. (15mL)

KC Pharmaceuticals, Inc. Pomona, CA 91768 Questions? Call 1-888-527-4276 Made in USA

EYE DROPS REGULAR

tetrahydrozoline hydrochloride solution/ drops

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55651-005

LOT EXP

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TETRAHYDRO ZOLINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZOLINE - UNII:S9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
BORIC ACID (UNII: R57ZHV85D4)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		

WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

I	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55651-005- 01	1 in 1 CARTON	08/28/2003	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	08/28/2003	

Labeler - KC Pharmaceuticals, Inc. (174450460)

Establishment			
Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(55651-005), pack(55651-005), label(55651-005)

Revised: 10/2019 KC Pharmaceuticals, Inc.